FTS-OD OAM

Moderator: Morgan Jackson
August 17, 2006
3:00 PM ET

Morgan Jackson: We scheduled this one hour meeting to discuss the program announcement, *CAM at Minority Health or Health Disparities Research Centers (PAR-06-372)*, which is a reissue of (PAR-05-152).

As you know, we have had two previous conference calls on May 11, 2006, when we discussed the review process and how to read your summary statements, and on June 29, 2006, when we discussed strategies and tips for revising your application. Transcripts for those calls are posted on NCCAM's Website. The theme of today's technical assistance conference call is NIH's new electronic application process and the new grant application form, SF-424.

And now a word from our sponsors. These telephone conference calls are open to any potential applicants, and we hope you find them useful. We invite you to share information about them with your colleagues, but in a variety of ways, it helps us to know who is participating on the calls. So, if you haven't already done so, we ask that you please send the requested registration information to the Website we used for communications regarding these calls.

And now back to our regular scheduled program already in progress. Joining me today here at NCCAM are Dr. Martin Goldrosen, Director of NCCAM's Division of Extramural Affairs, who has responsibility for NCCAM's Grant

Review Process, and Dr. Peter Kozel, who works with me on Special Population issues.

As background for this conference call, we sent you two PowerPoint presentations. The presentation labeled *NIH Grant Review Process* is for your information. It was developed and used by Dr. Partap Khalsa who joined us on the May 2006 conference call. I apologize for not editing some of the content of that presentation which was more appropriate for that presentation than it is for this one. The other presentation, *NIH Electronic Submission Overview*, was developed by Dr. Goldrosen and is the basis for his remarks today.

As with previous conference calls, this one is being recorded. A transcript will be posted on NCCAM's Website to the supplemental information for applicant's Website for PAR-06-372. After Dr. Goldrosen's presentation, I want to emphasize a few points regarding the grant application review process, and then we'll answer questions for the remainder of the hour. With that, I'll turn it over to Dr. Goldrosen.

Martin Goldrosen: Good afternoon, everyone. What I'd like to do is give you an overview of the new electronic format, and how it's going to impact the way you submit an amended application to NIH. What I'm going to do is go through my slide set that you have. I'm not going to be able to answer specific technical questions. What I am going to be able to do is give you a global overview so you understand what the new process is all about. If you understand what the new process is all about, I think it'll be easier for you to navigate the system.

We're going to do two things. One is to tell you about why we're converting over and how one does it; and then two, tell you about the resources that are available in case you have any problems.

By the end of May 2007, NIH will require that all grants be submitted electronically through Grants.gov, and will transition from the 398 form which has been used for approximately 50 years to the SF-424 family of forms. So we really have two elements that are changing: one, going from paper to electronic; and two, going from the 398 form to the 424 form. Don't be fazed about the transition from the 398 to the 424 form because as you will see, the 398 actually is still embedded in the 424 form. Think of the 424 as the outer wrapping of the grant application; the meat of the grant application is still the 398.

This transition is occurring not only in NIH, it's happening all across the government. There are roughly 27 agencies in the government that hand out money and all of them will be transitioning to this 424 form by the end of 2007. The main reason for this is that the American grant community has asked the government to use a common interface for all grant applications. If you really think about these 27 different agencies, each and every one of them uses a different form. If you have a business office that applies to multiple agencies, then you're faced with the proposition of learning how to apply through a government agency that has a different form each time. So the idea was to try to simplify it for you as an applicant and then to allow you to do it in electronic format.

This transition from paper to electronic is a transition that impacts all of us, not only you as the applicants, but we as your scientific administrators. It involves many funding mechanisms and tens of thousands of applications ranging in the size of five pages for the entire application to applications running into thousands of pages.

There are essentially two different systems that work together in order for this to work in its totality. One is Grants.gov, and the second is the eRA Commons. Grants.gov is the Federal government's single online portal to which all the applications are initially sent. All 26 federal grant-making agencies will use this one portal. The second part of the system is the eRA Commons. That is the part of NIH which receives the grants that you send to Grants.gov in electronic format and delivers them to our door: You submit in to Grants.gov and we harvest them from the Grants.gov. Each system has its own registration and validation process, and you must register for both.

Now the "you" is essentially two different people. The "you" is you as an applicant, and the "you" is you as your business office official or authorized institutional representative (AOR). You as the applicant do not have to register at Grants.gov, but your business office does have to register at Grants.gov. Additionally, both you and your business office have to register in the eRA Commons, and both sets of registrations have to be complete prior to submitting your application. It can take between two to four weeks for both sets of registrations to occur. So my suggestion to you is that if you or your institution hasn't yet registered in eRA Commons, the first thing you should do is go through the registration process.

In order for both you as an individual and your applicant organization to register, you have to get a DUNS number, which is Data Universal Numbering System from Dun & Bradstreet. Then, you have to go into the CCR to give that number. You have to obtain your DUNS number and use it in CCR to get another number. That in and of itself can take some time.

As I said, the applicant organizations only have to go through a one time registration. You as a PI (principal investigator) have to be registered by your university in the eRA Commons. If you have served as a reviewer for us in

the past, you only have what is referred to as a provisional registration. That means that all the information needed for you to come in as an applicant is not there, and your university or research institute has to update your information in the eRA Commons. Because it does take a period of time for the registration to occur, as long as you've made a good faith effort in registering – meaning that you began the registration process at least two weeks in advance of your grant's submission date, - we will not hold it against you if you have difficulty getting through the systems because of registration issues.

There are two ways for you to submit an application to NIH through Grants.gov. One is using the PureEdge Viewer, and the other is to do a system-to-system transfer using the XML data stream. If you're using PureEdge Viewer, you can actually download the software from one of our websites. I believe it's on Grants.gov, and it's available for free to you. If you're going to use XML data stream, then you can use either a package that your institution has purchased or there are commercial service providers out there who can actually do the transfer for you.

Mac users have an issue in that they will need to use the ECA PC Emulation software or download a free Citrix client application to take advantage of the Citrix service offered by Grants.gov in partnership with NIH. One of the commitments of the software company that has set up Grants.gov is to be able to provide a seamless integration between the PC and the Grants.gov Website by some time in November 2006. These applications are due November 14th , so I wouldn't count on that option being available if you're a Mac user.

The application form and the instructions are available through two sources. You can go into the Grants.gov website where they're available for download, or you can go to NCCAM's website and there will be information for each of our announcements, as well as directions on how to apply.

Each of the applications is now referred to locally as a Funding Opportunity Announcement. We still use the terms PA, PAR and RFA at NIH, but globally, they're known as Funding Opportunity Announcements (FOA). What you're going to do is download a package for a specific FOA. In your case, we're going to download the Funding Opportunity Announcement 06-372. That's the one you want to use. Please be advised that you cannot use the forms from one FOA for another FOA.

The second place where you'll find information is in the NIH Guide to Grants and Contracts which directs you to Grants.gov. There you'll find both the software as well as the actual FOA that you will download into the software.

In the last month or so, NIH and all of the 26 or so government agencies have upgraded from Version 1.0 of the SF-424 form to Version 2.0. In the process of doing so, we have re-uploaded every single FOA. In the process of doing so, there's a very small window where both Version 1.0 and Version 2.0 FOAs were available online. When you apply, make sure that the SF-424 forms have Version 2.0 on them, not Version 1.0, because once you fill them out and try to use Version 1.0, Grants.gov will not accept it. Does anyone have any questions at this point?

Participant 1: Yes, once the application is submitted, is it printed on your end or is it maintained in its electronic format completely and totally through the application process including final disposition of the application?

Martin Goldrosen: Once it comes in electronically, we'll probably keep it in electronic format.

Participant 1: The second thing is how does one apply for a DUNS number?

Martin Goldrosen: That I didn't really address in my talk, and I don't believe there's any information in the slides. I haven't come to it, but Dr. Jackson's checking on it. If I don't have a slide that specifically directs you to that question, we'll send out information to you on how you apply for a DUNS number.

Participant 1: Thank you.

Martin Goldrosen: If there are no other questions, what I want to do now is go over the process globally. What are the different steps you do? Some of them we've talked about. First, you want to identify a grant opportunity. In your case, it's already picked – we're talking here about a specific FOA. You download the grant application form, complete the application, and then save it on you computer. Then, your Authorized Organization Representative or AOR, the business person, submits the application to Grants.gov either directly or through a service provider on your behalf. You the scientist cannot submit an application yourself, but must rather submit it through the AOR. Remember: in order to apply for a grant, all the registrations need to be complete or else the system will not be able to recognize you.

Participant 1: Let me ask one other question. Can you apply at anytime even if your application is not due for weeks and months?

Martin Goldrosen: No. There are windows of opportunity for you to apply. There are called "open periods". We'll get through that in a couple of slides down.

Once you submit the application to Grants.gov, the system will perform a validation check and a virus check on the submitted application. It will then get a tracking number and then everyday the eRA Commons or NIH harvests grants from Grants.gov which are directed to our Funding Opportunity Announcements. We then do another series of validations. Each step in

Grants.gov takes two days and in eRA Commons it also takes two days. You should receive emails from both Grants.gov and/or the eRA Commons saying that they have received your application, but we cannot guarantee that you will get the email. So, the onus is on you and your business official to check. You can't check at Grants.gov but you can actually go to eRA Commons to check on the status of your grant application.

Once you find out that your grant application is in the eRA Commons, you have two days to review it to make sure that the application that you submitted is in fact the application that we have on file in the eRA Commons. If there is any issue with this, you can reject it within that two-day period, make corrections, and resubmit it to Grants.gov. Anytime you have to resubmit an application, you don't submit it to us but you always have to go through Grants.gov and you have to label it as a resubmission. There is a cover sheet where you provide us information saying that the application was submitted on such and such a date, it was in the eRA Commons and you noticed the following errors and because of these errors you decided to resubmit it.

There are two different kinds of warning messages that you may get. One warning will say that your application has a fatal flaw, cannot go forward and needs to be corrected. The other one says, your application is not quite perfect but it's up to you to decide whether you want it corrected or go on. Those two kinds of warnings are clearly delineated.

After it has gone through both the Grants.gov and the eRA Commons, the application will be saved and the grant image will be available in the system. The other thing that the eRA Commons does is assemble it into an actual grant application. As I will explain to you, what you're submitting is not an actual grant application, but you're submitting individual PDF files – components of

a grant application. What we eventually do, at this end, is collate them electronically into a single grant image.

My slide Number 18 says that the registration process can take two to four weeks and that's why we suggest that you start the application process four weeks in advance of the submission date. Remember, both Grants.gov and eRA Commons each requires two business days to process an application. Within those two – two business day periods, you decide whether you want to accept or reject the application.

So let's go on to discuss what the application looks like from your end once you download the Pure Edge software and have opened the Funding Opportunity Announcement. You'll see on the left-hand side there are two boxes in red: One talks about mandatory documents and the other talks about optional documents. You open the mandatory documents, fill out the information and once the information is complete, save it on your hard drive and move it to the right-hand side, where it says, "Mandatory complete documents for submission."

An example of the optional document is the cover letter. In this cover letter you can state that this is a resubmission; you can state that this is an application that you're submitting in response to a FOA from NCCAM. If this is another application that you are submitting to a different FOA and you want it to go a specific review group, you can suggest a specific review group. This is the place where you put that kind of information.

A complete application to NIH will have both the 424 forms which are the outer shell, and the 398 components, which are the meat of the application. The application that you have worked on in the past, Sections A - D are really the 398 portion of the application.

Most of the attachments that you submit are individual files. For NIH, all these files have to be in PDF format. You can type them in Microsoft Word or another word processing program, but you have to convert them to PDF format in order for the system to be able to accept the individual files.

Slide Number 22 talks about the SF-424 form, including the cover page, which is essentially now two cover pages; the senior and key people; the budget; and the amount of time that you are going to devote to this proposed project. One of the other shifts we've incorporated in this transition is that the NIH no longer refers to percent effort, but rather person months. The reason we did so is that in most universities, people don't work 12 months - they may work nine months. The term "person months" takes into account the difference between nine month appointments and 12 month appointments.

For the 398 portion, you create individual PDF files for the cover page, the modular budget, if you don't fill out the budget in the SF-424 portion, the research plan, and the checklist. The cover page, if you have it, will not go forward with your grant. Once you send your application for the reviewers, we will not send the cover page along; that is for our internal information purposes only. When you prepare Sections A - D, which constitute the research plan -- the significance, the background, the methods, etc. -- follow the 398 format in terms of page limits, margins, and font size.

Currently, we accept up to ten separate attachments for appendix material. There is an internal discussion at NIH regarding appendix material that does not apply to your grant application at this point. The NIH is considering accepting a modified appendix section at some time in the future. The modification will be such that we will no longer accept reprints but we will expect you to give us the URL for those reprints if they're available in a

common database (such as through PubMed, as an example). We will no longer accept images -- pictures of items that you have in the grant -- because the images in the grant now are of sufficient quality such that we don't need separate images of things such as gels. These are the changes that we anticipate in the future; they have not become practice. I'm just telling you that so you are aware of what will happen over the next six months.

Once your grant is in the eRA Commons, the Commons software will assemble a grant image, generate the table of contents, and will create headers and footers. I'm going to stop here and allow you to ask any other question you might have about the mechanics of creating a grant. Does anyone have any question to this point?

Participant 2: I have a question about the ten separate attachments. How many pages are allowed per attachment?

Martin Goldrosen: At this point there are no limits on the length of those attachments.

Participant 3: I have a question about clarification for the 398: Are we going to use the same forms for the Table of Contents and Sections A through D for this conversion into the PDF files?

Martin Goldrosen: Correct. Are there any other questions?

Okay. The two other areas I want to talk about are the terminology that we use, and then the timeline.

The terminology that has been in vogue at the NIH for the last 50 or so years is now passé. With the SF424, we're now using the terminology that the government in general is using for grant applications.

The next two or three slides go over the terminology we used in the past and what we will now follow in the future. A Type 1 application in both the old and the new terminology is still called a new application. If you send in a competitive renewal -- which is not your case because they're applying really as an amended application – such an application would now be referred to as renewal. That is if you're going to get funded this time around, you worked on it for a period of time. This FOA does not allow renewals because it is an R21. So, to take a hypothetical example, let's say you submitted an R01, the so-called conventional grant application, and your application was funded for three years. At some point, you would submit what we currently call a "competing continuation" or "type 2" application for an additional 3 years of funding. In the new terminology, this would be called a "renewal".

Let's now talk about the changes in terminology that appropriate to your case. You have already submitted a "new" application, also called a "type 1." These sorts of applications will continue to be called "new" applications. Right now, you are likely preparing what we currently call a "revision" to an application. Under the new terminology, this will be called a "resubmission."

As I said before, we will refer to all of these funding mechanisms in the future as funding opportunity announcements (FOAs) but we still use the terms "PA" and "RFA". The other terminology is not critical and you have the handout as a reference guide for future, so I won't go over it.

The final thing I want to talk to you about is our transition strategy. We decided that we wouldn't do a conversion of all our grant mechanisms at once, but rather we would set up a phasing plan. We established this transition in part because we ourselves have to gain experience with the new systems, and, two, because we're talking about thousands and thousands of applications

coming in to a single portal. The NIH wants the portal to be able to handle large volumes of applications. Consequently, we spread out the way in which we have been receiving these.

The process has now begun with SBIRs and STTRs which are small business grant applications. Conference grants (R13s) and AREA grants (R15s) have already transitioned over. For NCCAM, the big one will be R21s, which will start coming in on June 1st. We're having this teleconference because you're submitting R21 applications which you will have to submit electronically. The next major receipt date will be for R01s which will be February 1, 2007. There is a learning curve on everyone's behalf and, in our experience, it will take you more than one try to get your application accepted by Grants.gov. If your application is bounced back the first time, don't take this as an ultimate rejection; on average people are taking two shots to get their applications in the front door to Grants.gov.

The final part of my presentation talks about a question that I was asked: When can you start working on your application? You can start working on your application as soon as it is available in Grants.gov or on the NIH Guide which transfers you to Grants.gov. Generally, we like to publish these FOAs about two to four months before they're due. So as soon as they're open and you're told that they exist, you can download the software and start working on your application.

The application will tell you the opening date and the submission date. The opening date is the first day that a completed application can be submitted to Grants.gov, and is generally a month before the actual submission date.

The following slides are self-help slides and I won't go through them in any detail. There is an NIH help desk for you and there's a number you can call to

speak to a person who can help troubleshoot your specific problem. If they can't troubleshoot your specific problem, they will write up a ticket and then you will get a respond in a period of time -- they'll give your ticket to someone who can actually handle it. The number is the eRA Commons help desk and it's on Slide Number 38, the second to the last bullet has the number to the eRA help desk. With that, I will stop my presentation and will be happy to answer any other questions, clarify any other issues you have.

Morgan Jackson: And on the DUNS.

Martin Goldrosen: Yes, Dr. Morgan Jackson and Dr. Peter Kozel actually found the information for the DUNS number and I will tell you what it is.

Peter Kozel: We found it on Grants.gov and I'll try to read the address. It's http://grants.gov/applicants/request_duns_number.jsp. If you don't want to type the address in but rather if you just want to navigate, the easiest way is to log on to Grants.gov, go to "Get Registered", click "Organization Registration," then click on "Registering your Organization," and then on "Request a DUNS Number," and that will take you to where you can go to get information request for a DUNS number and send you to an external website to apply for that number.

Morgan Jackson: Other questions for Dr. Goldrosen?

Participant 4: If you already have a DUNS number, is that okay or do you have to get another one?

Martin Goldrosen: If you have a DUNS number, you're okay. But what you do need to do is to get a full registration in the eRA Commons which is different from the

registration you have if you've served as a reviewer. So you're one step ahead.

Participant 4: Thank you.

Participant 5: I have a question: When you have saved these materials offline, how do you get the submission page to recognize your offline documents?

Martin Goldrosen: I've been asked that question before. You can't submit the application. Your authorized organization representative, AOR, who is somebody in your business office, has to submit the application to Grants.gov of your behalf. So what you have to do is speak to them on how they want you to transfer electronically your files, your PDF files that make up your grant application, to their system so they can upload it. How it's done internally at other places, I don't know.

Participant 5: It's all right. It's just that when I was trying to work on your page yesterday and I was seeing if I save the documents did they really save and whatnot, I couldn't figure out how I could get it back in your mandatory complete documents for submission. But you're saying it's within my business office, so I'll check with them.

Martin Goldrosen: Yes.

Participant 6: So what you're saying is that people in the business office are the only ones who could submit the application to Grants.gov?

Martin Goldrosen: Yes, they're the only ones who can submit it, and two, they can only submit it using PureEdge software or was it XML transfer. The reason for this is that we don't have a relationship with you. Even though you're preparing the

grant application, our business relationship is with your university or institution. What's happening is that by asking them to submit it on your behalf, they're guaranteeing that they're offering you the space, facilities, etc., to do what you're proposing to do.

Morgan Jackson: This is equivalent to having the institutional official sign the face page of your 398 grant application.

Martin Goldrosen: That's right.

Morgan Jackson: Any other questions? So let's see, they were a few minutes left. I had wanted to go over some points. Let me first ask if there were any questions on the presentation called the NIH Grant Review Process that was the other document that accompanied Dr. Goldrosen's PowerPoint handout.

Peter Kozel: Actually, if I may interject, these documents were sent not as PowerPoint slides but rather as PDF handouts that contains two slides per page. And so, if you didn't see a PowerPoint file, you may be looking for the wrong tile type. We didn't send you the actual raw slides. We sent you a PDF file that contains slides. I just wanted to correct that.

Morgan Jackson: Thank you. There were a few points that I had come across in another presentation from a staff person relevant to the grant review process. Dr. Laurie Donze had given a presentation that provided information on some aspects of review that I wanted to share with you that I thought could help illuminate certain aspects of it.

First I wanted to mention what happens in a review meeting, to give you some background about what happens to your application once it gets submitted.

The SRA, the Scientific Review Administrator who's the government official responsible for conducting a review, completes the content and the administrative review to make sure that the components of the application are present, recruits the panel members and makes assignments. The reviewers read the assigned applications, write critiques, and assign preliminary scores. The SRA, in the course of the meeting, reviews the administrative, confidentiality, and conflict of interest policies. There is a chairperson, who is not a Federal individual but rather an outside expert, who guides the scientific discussion of each application. All reviewers participate in the discussion and scoring of all applications unless there is a conflict. If a reviewer is in conflict, he/she will leave the room.

Deleted: ,

The reviewers assign scores, their preliminary scores in the 1.0 to 5.0 range. The primary reviewer then presents an overview of the application and his/her own evaluation. Reviewers two and three discuss points of agreement or disagreement, and then other reviewers may ask questions or join in their discussion which is moderated by the chair.

Deleted: add

After the discussion of the application, the assigned reviewers present their final scores. All reviewers score the application within the range of scores set by the assigned reviewers, or a narrow margin outside of that. If a reviewer votes outside of that range, that reviewer must speak up and justify their score. In terms of the summary statement, the summary statement is a written report of the results of the review.

Scores are generally available on the NIH Commons within one week after meeting and the summary statements are available on the NIH Commons approximately two months after the meeting.

The PI -- the candidate applicant -- must have an NIH Commons account in order to access the scores and the summary statements, and the PO, the program officer, here at NCCAM, can discuss the scores and the summary statement only with the principal investigator who has submitted the application. I see that I came in the middle of my notes, and so I'm going to have to go back.

The reviewers generally are experienced CAM investigators, people who are expert in various areas covered by the applications. Typically they're 20 to 25 reviewers at each meeting. Each application is assigned to three to four reviewers to read and evaluate. The reviewers are assigned to applications based on their expertise in the principal investigator's discipline, the CAM modalities to be studied, the diseases to be studied, or the research methods proposed. Previous reviewers are invited and assigned if available for resubmissions, such as the case here. They may join the review by telephone if they're unable to attend in person.

All reviewers have access to previous summary statements and are encouraged to consider the responses to the prior review in their critiques. One of the things reviewers will be looking for in these application is how well you improved you application in general but also how well this resubmission addresses the concerns articulated in the previous summary statement. Each mechanism has unique review criteria. It is important to read the FOA carefully especially the specific review criteria used in the FOA.

In submitting the application and revising your application, it's important that you be explicit about changes that you're making and identify the revisions in the application. If additional data are available, those should be included, and it's also helpful for you to update your literature search to see if you could strengthen your application by updating your publications list.

I said before and I'll repeat it again, your application is to document a persuasion as well as a document of information.

When you come across critiques in the summary statement, you do not have to accept the criticisms but you need to address them all in a cordial, thoughtful, and respectful way. You need to make certain that there is sufficient information in the application to convince expert reviewers that you know what you're doing, as well as enough background information to inform a general reviewer. It's important that you not assume that the reviewers will know what you mean. Also, because the review committee may have new participants, the revision should seek to address any identified weaknesses, not just the summary statement critiques. Merely changing the application in response of the summary statement does not guarantee funding.

As Dr. Goldrosen said, please begin your registration process early. We recommend about a month before the receipt date – when the system opens. The receipt date is November 14th. The system should open around October 14th or 15th. We're actually recommending that you begin the registration process by at least September 15th. We also suggest that you begin the electronic submission process by around October 14th, when system opens, but not later than October 31st.

One point that Dr. Goldrosen made was that a good faith effort would be considered an application process that began two weeks prior to the receipt date of November 14. So please make sure that you're beginning the application submission process by about October 31st or November 1st.

Are there other questions that people might have at this time?

Participant 6: How many pages can the introduction be?

N.B. – this information was added after the conference call: Applicants may use up to three pages for the Introduction.

Formatted: Font: Bold
Formatted: Font: Bold
Formatted: Font: Bold

Martin Goldrosen: We'll have to get to you. We're going to have Dr. Kozel send an email with clarification. The reason I'm hesitating is that in the past, we've allowed application - we're talking about the introduction, right, which basically states how you changed your application?

Peter Kozel: No.

Martin Goldrosen: Don't do it in a question-response format. Don't waste space by saying reviewer one stated and take up half a page with what reviewer one stated. What you want to do is simply state the changes you are making to the application and, two, in the actual text, you have to denote where the changes are found by underlining the text, or if you can make a mark in the margins. That would be the best way of handling it.

This announcement uses both our basic and clinical. This FOA refers to two different announcements. Either you're going to use the basic and pre-clinical or the clinical program announcement, and unfortunately, they differ. The basic one I believe allows one page. A clinical application may use three pages for the introduction.

Martin Goldrosen: We will send a clarifying email to all applicants. (N.B., this was done in September 2006.). So what you have to do is look at the FOA that you're using as a model. You're not going to put your application in to one of NCCAM's model FOAs, the basic and pre-clinical (PAR-06-315), or the clinical FOA (PAR-06-510). You're submitting your application to PAR-06-

372. But you're going to use the information from the other NCCAM FOA as a basis for formatting your application.

Did that make sense? Or have I talked to the point where I've confused everybody? You can be honest with me. I'm not going to sulk and cry. Did I make sense to you or not?

Participant 6: I understand that we are not clear on whether it needs to be one or three pages, and that we're supposed to use the forms that are with the PAR-06-372. But the other piece that you just said that we need to refer to, I'm not clear on.

Martin Goldrosen: Okay. If you read the fine details of PAR-06-372, it actually refers you in terms of formatting issues, number of pages, number of years, the budget, this kind of thing, to one of two different NCCAM program announcements, PAR -06-315, the basic and pre-clinical FOA. So if you have an application that does not involve human subjects, you're using an animal model, you'll use the formatting questions, the number of pages, the budget, the number of years, the number of pages allowed for the introduction, which is one, as the basis for you to fill out the forms for PAR-06-372.

If it is the clinical program announcement, PAR-06-510, which is our clinical FOA, you'll notice that the budget is different, the years are different, the pages are different, and the introduction is different. You have to know which one you're using as your model.

Participant 7: This makes me a little confused. I thought that the clinical research is the one that involves an intervention and the pre-clinical is the one that does not involves an intervention.

Deleted: I thought that.

Morgan Jackson: No, clinical research is determined by the involvement of human subjects or even human tissue. Without identifying yourself, can you generically describe the kind of activity that you're undertaking?

Deleted: itself

Participant 7: Yeah, I'm using the focus group and the survey.

Morgan Jackson: That definitely includes human subjects and that's definitely clinical.

Participant 7: Oh, okay. So I can ask for three years.

Morgan Jackson: Yes. You can ask for three years, and you can ask for a budget of up to $400,000 direct costs with no more than $250,000 direct costs in any one year. Basic and pre-clinical is for test tubes, tissue cultures, animals and things like that.

Deleted: ¶

Deleted: Participant 7: Okay.¶
¶
Morgan Jackson:

Participant 7: Okay. That's good to know. Thank you.

Morgan Jackson: Any other questions? If not, I thank you for your time. It's 4:05; about an hour after we started. I want to emphasized that if you have any questions at all, please feel free to contact me or Dr. Kozel. We will be sending an email with the clarification about the number of pages permitted on introductions. There is longer story than you care to here that would go into explaining why there is uncertainty about that. We will send you the instruction.

Please begin the registration process early. Please begin the submission process early. Feel free to call me if you have any questions. I thank you for your time and wish for you all the best with your revised application.

END